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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,700	08/10/2007	Graham W. Burton	50248/005002	8804

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

NIELSEN, THOR B

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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03/17/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/589,700	Applicant(s) BURTON ET AL.	
	Examiner THOR NIELSEN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>March 26, 2007</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of Claims

Claims 1-48 are pending in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The person of ordinary skill in the art is suggested to be one with the skill of the inventors and/or authors of the references cited against the instant application.

Claims 1-3, 5, 10, 21, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,532 (Jager-Lezer).

Applicant Claims

Applicants claim a composition for topical administration comprising an oxidatively transformed carotenoid, a method of treating a skin condition using the composition, a container having the composition, and a composition having oxidatively transformed carotenoid and an antioxidant. In some embodiments, the carotenoid is 2-methyl-6-oxo-2,4-heptadienal.

Scope and Contents of the Prior Art

Jager-Lezer is directed to cosmetic compositions. Title. The compositions can have carotenoids such as stabilizing vitamins, carotenes, vitamin A, and lycopene. Column 6, lines 48-53. The amount of carotene, vitamin A, etc. can be from 0.01 to 20 %. Column 6, lines 58-62. The composition can have an emulsifier and can be a lotion or cream. Column 7, lines 2-14 and lines 46-51. The composition is used for cleansing skin or treating skin and as a cosmetic. Column 8, lines 54-68. Moreover, Jager-Lezer discloses compositions having 0.05 wt. % disodium EDTA, a metal chelator which is also an antioxidant. Column 10, line 57. The

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reference also teaches octyl isononanoate, a lower alcohol fatty acid ester, as a component of the cream composition. Column 10, line 46.

Ascertainment of the Difference between the Scope of the Prior Art and the Claims (MPEP § 2141.012)

Jager-Lezer does not exemplify the claimed composition.

The skilled artisan would have a reasonable expectation of success because Jager-Lezer exemplifies other labile oil formulations.

**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention upon reading Jager-Lezer to prepare a formulation by consolidating teachings found in the single reference because Jager-Lezer is directed to compositions for stabilizing an oxidizable active principle and use of those compositions. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,532 (Jager-Lezer) in view of US 6433025 (Lorenz).

Scope and Contents of the Prior Art

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The disclosure of Jager-Lezer is provided above.

Lorenz is directed to use of carotenoids for prevention or retardation of sunburn.

Abstract. In particular, Lorenz discloses that **topical application of Vitamin E** is useful in preventing sun-induced inflammation, skin sensitivity, and skin damage. Column 3, lines 56-60.

Lorenz also contemplates use of topical sunscreens that can have para-**amino benzoic acid esters, cinnamates, salicylates, and benzophenones**. Column 5, lines 15-24. Lorenz further teaches the role of histamine in sunburn. Column 3, lines 12-14.

Ascertainment of the Difference between the Scope of the Prior Art and the Claims (MPEP § 2141.012)

Jager-Lezer does not exemplify a composition having Vitamin E or sunscreen agents. Lorenz discloses use of Vitamin E and thereby corrects the deficiency. Lorenz also discloses sunscreen agents.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP § 2142-2143)

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer and Lorenz because both are directed to carotenoids and both teach topical formulations for skin care. It is reasonable to combine materials used for the same purpose. The skilled artisan would have a reasonable expectation of success combining the teachings of the cite prior art references, because Lorenz advises that Vitamin E is effective and that also carotenoids are effective. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the

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invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,532 (Jager-Lezer) in view of US 5759528 (Yamada).

Scope and Contents of the Prior Art

The disclosure of Jager-Lezer is provided above.

Yamada is directed to topical compositions for transdermal absorption of therapeutic agents. Abstract. Yamada discloses that topical skin medicines can have diphenhydramine, hydrocortisone butyrate, fluocinolone acetonide, betamethasone valerate, or dexamethasone. Column 6, line 56 to column 7, line 17. Yamada also discloses that carotenoids are useful in topical skin medicines. Column 2, lines 20-30.

Ascertainment of the Difference between the Scope of the Prior Art and the Claims (MPEP § 2141.012)

Jager-Lezer does not exemplify a composition having an antihistamine or a corticosteroid. Yamada discloses use of diphenhydramine and several corticosteroids, and thereby corrects the deficiency. Yamada also discloses use of carotenoids.

The skilled artisan would have a reasonable expectation of success because Yamada advises that diphenhydramine is useful and that also carotenoids are effective.

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**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer and Yamada because both are disclose use of carotenoids and both teach topical formulations for skin care. It is reasonable to combine materials used for the same purpose. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 11, 12, 13, 15, 20, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,532 (Jager-Lezer) in view of US 2003/0096875 (Burton).

Scope and Contents of the Prior Art

The disclosure of Jager-Lezer is provided above.

Burton is directed to oxidized carotenoid fractions. [0009]. Oxidized carotenoid fractions can include Vitamin A [0004], 2-methyl-6-oxo-2,4-heptadienal [0012], and other products [0005]. Therapeutically effective amounts are disclosed, including concentrations encompassed by the claimed range, as can be readily found by back-calculation using the data provided in paragraphs [0083] and [0085]. Specifically, Burton discloses 0.001 to 0.02 wt. %. Id. Carotenoids such as beta-carotene have antioxidant properties. [0004]. The agents can be administered topically. [0026]. Burton further discloses that excipients can include stearic acid (a fatty acid). [00173].

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**Ascertainment of the Difference between the Scope of the Prior Art and the Claims
(MPEP § 2141.012)**

Jager-Lezer does not exemplify a composition having 2-methyl-6-oxo-2,4-heptadienal nor is it relied on for disclosure of a fatty acid. Burton discloses 2-methyl-6-oxo-2,4-heptadienal and stearic acid and thereby provides the disclosure missing Jager-Lezer.

**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer and Burton because both are disclose use of carotenoids and both teach topical formulations for skin treatment. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager-Lezer in view of Lorenz further in view of Burton.

Scope and Contents of the Prior Art

The disclosure of Jager-Lezer, Lorenz, and Burton are provided above.

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**Ascertainment of the Difference between the Scope of the Prior Art and the Claims
(MPEP § 2141.012)**

Jager-Lezer does not exemplify a composition having Vitamin E, sunscreen agents, or 2-methyl-6-oxo-2,4-heptadienal. Lorenz discloses use of Vitamin E and thereby corrects this deficiency. Lorenz also discloses sunscreen agents. Burton discloses 2-methyl-6-oxo-2,4-heptadienal and supplies this deficiency.

**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer, Lorenz, and Burton because all are directed to carotenoids and all teach topical formulations for skin care. It is reasonable to combine materials used for the same purpose. The skilled artisan would have a reasonable expectation of success because Lorenz advises that Vitamin E is effective and that also carotenoids are effective. Moreover, Burton discloses that 2-methyl-6-oxo-2,4-heptadienal is a carotenoid effective for skin treatment for anti-cancer and other uses. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager-Lezer in view of Yamada further in view of Burton.

Scope and Contents of the Prior Art

The disclosures of Jager-Lezer, Yamada, and Burton are provided above.

Ascertainment of the Difference between the Scope of the Prior Art and the Claims (MPEP § 2141.012)

Jager-Lezer does not exemplify a composition having 2-methyl-6-oxo-2,4-heptadienal, an antihistamine or a corticosteroid. Yamada discloses use of diphenhydramine and several corticosteroids, and thereby corrects the deficiency. Yamada also discloses use of carotenoids. In addition, Burton discloses 2-methyl-6-oxo-2,4-heptadienal and cures that deficiency.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP § 2142-2143)

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer, Yamada, and Burton because all disclose use of carotenoids and also teach topical formulations for skin care. It is reasonable to combine materials used for the same purpose. The skilled artisan would have a reasonable expectation of success because Yamada advises that diphenhydramine is useful and that also carotenoids are effective. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 22-30, 32-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager-Lezer in view of Burton further in view of US 5665776 (Yu).

Scope and Contents of the Prior Art

The disclosures of Jager-Lezer and Burton are provided above.

Yu is directed to additives for **enhancing topical actions of therapeutic agents**.

Abstract. Yu discloses compositions useful for treatment of **dandruff**, dry skin, **eczema**, and **warts**. Column 1, lines 12-16. Yu's formulations are useful for **psoriasis** treatment and can contain **anthralin**. Column 8, lines 18-19. Yu's formulations are also useful for treatment of **photoaging of skin** and can have **retinoic acid**. Column 20, line 51 to column 21, line 7. With specific regard to **eczema**, Yu discloses use of **betamethasone dipropionate**, which is a corticosteroid. Column 16, lines 11-13. Furthermore, Yu discloses **ketoconazole**. Column 19, lines 31-34.

Ascertainment of the Difference between the Scope of the Prior Art and the Claims (MPEP § 2141.012)

The combination of Jager-Lezer and Burton discloses a method of treating skin by applying a composition having oxidized carotenoids to the skin. The combination of Jager-Lezer and Burton is not, however, relied on to disclose certain skin conditions including dandruff, dry skin, eczema, warts, psoriasis, or photoaging of skin. Yu discloses these skin conditions and topical treatments for these conditions and thereby cures the deficiency. Jager-Lezer and Burton are also not relied on to disclose agents that can be used for treatment of these skin conditions, including anthralin, retinoic acid, corticosteroids such as betamethasone dipropionate, or ketoconazole. Yu discloses these agents and thereby cures the deficiency.

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**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer , Burton, and Yu because all the references are directed to topical formulations for skin care. Moreover, one of skill in the art would recognize that Yu teaches that the agents can usefully be applied for the treatment of skin conditions. The skilled artisan would have a reasonable expectation of success in applying these agents taught by Yu, because Yu advises that each of these agents is useful and effective. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 31 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager-Lezer in view of Burton further in view of Yu, yet further in view of Yamada.

Scope and Contents of the Prior Art

The disclosures of Jager-Lezer, Burton, Yamada, and Yu are provided above.

**Ascertainment of the Difference between the Scope of the Prior Art and the Claims
(MPEP § 2141.012)**

The combination of Jager-Lezer and Burton discloses a method of treating skin by applying a composition having oxidized carotenoids to the skin. Yu teaches that eczema is a skin condition that can be treated. This combination of references is not, however, relied on to

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disclose use of antihistamines. Yamada discloses use of antihistamines for topical treatment of skin conditions and thereby cures the deficiency.

**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer , Burton, and Yu because all the references are directed to topical formulations for skin care. Moreover, one of skill in the art would recognize that Yu teaches that the agents can usefully be applied for the treatment of skin conditions. It would further have been prima facie obvious to combine the teachings of these references with that of Yamada, because Yamada is also directed to therapeutic formulations for topical treatment of skin and discloses that carotenoids are useful for skin treatment.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager-Lezer in view of Burton further in view of US 6423743 (Romanczyk).

Scope and Contents of the Prior Art

The disclosures of Jager-Lezer and Burton are provided above.

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Romanczyk discloses antioxidant properties of carotenoids. Column 41, lines 58-62.

Romanczyk further discloses purging compositions contained in a bottle (i.e. a container) with helium to remove gas (e.g. oxygen). Column 48, lines 34-48.

**Ascertainment of the Difference between the Scope of the Prior Art and the Claims
(MPEP § 2141.012)**

The combination of Jager-Lezer and Burton discloses topical formulations having a carotenoid for treating skin. The combination of Jager-Lezer does not disclose putting the formulations in a container nor do the references disclose purging the container to remove gases such as oxygen. Romanczyk cures the deficit by disclosing purging compositions in a bottle by supplying helium.

**Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP § 2142-2143)**

It would have been prima facie obvious to a person of ordinary skill at the time of the instant invention to combine the disclosures of Jager-Lezer and Burton with that of Romanczyk because all the references are discuss carotenoids. Moreover, the skilled artisan, upon reading Jager-Lezer and Burton, would recognize from the disclosure in these references that the carotenoids are sensitive to oxidation, because they are antioxidants and would reasonably turn to Romanczyk as disclosing methods for dealing with oxidation because Romanczyk also discloses oxidation-sensitive agents. One of ordinary skill in the art would have a reasonable expectation of success in applying Romanczyk's method to the formulations provided by the combination of Jager-Lezer and Burton because it is well-known in the art to put formulations into containers. Moreover, it is well-known to stabilize compositions that are sensitive to

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oxygen, such as carotenoids, by removing oxygen, and that purging the gas phase is a common way to do so. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Conclusion

Claims 1-48 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOR NIELSEN whose telephone number is (571)270-3476. The examiner can normally be reached on Monday through Friday from 9:00 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thor Nielsen
Patent Examiner

/JAMES H ALSTRUM ACEVEDO/
Primary Examiner, Art Unit 1616